Heron Therapeutics Announces Positive Results from Phase 3 MAGIC Study of SUSTOL®

May 28, 2015

-Primary endpoint achieved

-SUSTOL, as part of a three-drug regimen, is the first 5-HT$_3$ antagonist to demonstrate superiority to standard-of-care for delayed nausea and vomiting after HEC

-SUSTOL-based regimen was associated with significantly reduced nausea and improved patient satisfaction

-Conference call and webcast Friday, May 29 at 8:30 A.M. ET

REDWOOD CITY, Calif.--(BUSINESS WIRE)--May 28, 2015-- Heron Therapeutics, Inc. (NASDAQ: HRTX) today announced positive, top-line results from its recently completed Phase 3 MAGIC study. MAGIC evaluated the efficacy and safety of the Company's 5-HT $_3$ receptor antagonist product candidate SUSTOL® (granisetron injection, extended release) as part of a three-drug regimen with the intravenous (IV) neurokinin-1 (NK_1) receptor antagonist fosaprepitant and the IV corticosteroid dexamethasone for the prevention of delayed-onset chemotherapy-induced nausea and vomiting (CINV) following administration of highly emetogenic chemotherapy (HEC) agents.

The MAGIC study is the only Phase 3 CINV prophylaxis study in a HEC population performed to-date to use as a comparator the currently recommended, standard-of-care, three-drug regimen: a 5-HT_3 receptor antagonist (in this case ondansetron), fosaprepitant and dexamethasone. The study was conducted entirely in the U.S. and enrolled over 900 patients undergoing HEC treatment for various tumor types.

The primary endpoint in this study was the proportion of patients who achieved a Complete Response, defined as no emesis and no rescue medications during the delayed-onset phase of CINV, occurring 24-120 hours following administration of HEC agents. The study's major efficacy findings include:

- The study's primary endpoint was achieved. The percentage of patients who achieved a Complete Response was significantly higher in the SUSTOL group than the comparator group (64.7% vs. 56.6%, p=0.014).
- The percentage of patients who achieved Complete Control, defined as Complete Response plus no more than mild nausea during the delayed-onset phase, also reached statistical significance in favor of SUSTOL (p = 0.022).
- The percentage of patients who experienced no nausea or infrequent nausea during the delayed-onset phase was significantly higher in the SUSTOL arm compared with the comparator arm (p = 0.032).
- Significantly more patients in the SUSTOL arm were satisfied with their therapy based on a quality-of-life questionnaire (p = 0.040).

SUSTOL was well tolerated, with no clinically significant differences in the rate or severity of adverse events between the SUSTOL arm and the comparator arm. Injection site reactions observed were consistent with previous trials and generally considered mild, as were the majority of adverse events observed in the study.

"The MAGIC study demonstrated that use of SUSTOL with an NK_1 receptor antagonist and dexamethasone for patients receiving HEC significantly reduced symptoms of CINV. It is significant that both arms of the study had a three-drug prophylactic regimen, which has not been previously evaluated in prior Phase 3 trials in this high-risk patient group. Symptom management in patients receiving cancer treatment represents a significant unmet medical need, and the results of this study represent another step forward in this important clinical space," stated Ian Schnadig, M.D., Principal Investigator, US Oncology Research, Compass Oncology, Tualatin, Oregon.

"The substantial benefit observed with SUSTOL in Complete Response, nausea and overall satisfaction with therapy is all the more impressive given the comparator was a three-drug, standard-of-care regimen. Also, unlike previous CINV studies, all patients in the MAGIC trial came from U.S.-based community oncology centers, so the results are highly representative of what we would expect to see in our patients," stated Jeffrey Vacirca, M.D., Principal Investigator, North Shore Hematology/Oncology Associates.

"We are extremely gratified to report that SUSTOL is the first 5-HT $_3$ receptor antagonist to demonstrate a statistically significant improvement in delayed nausea and vomiting in patients receiving HEC. As the first large clinical study to compare two three-drug regimens using the definition for HEC in the 2011 ASCO guidelines, the results reported today further demonstrate the potential for SUSTOL to be the foundation of the new standard-of-care injectable anti-emetic regimen," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "We look forward to presenting additional data from the MAGIC study at an appropriate upcoming scientific conference, but our immediate focus is now the resubmission of our New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA), which we expect in mid-2015. In addition, we are

planning for the commercial launch of SUSTOL, pending FDA approval."

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast on Friday, May 29 at 8:30 a.m. ET (5:30 a.m. PT). The conference call can be accessed by dialing (877) 311-5906 for domestic callers and (281) 241-6150 for international callers. Please provide the operator with the passcode "Heron" to join the conference call. The conference call will also be available via webcast under the investor relations section of Heron's website at www.herontx.com and will be archived there for 90 days following the call. Please connect to Heron's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

About the MAGIC Study

The MAGIC (**M**odified **A**bsorption **G**ranisetron **I**n the Prevention of **C**hemotherapy-Induced Nausea and Vomiting) study is a prospective, randomized, placebo-controlled, two-arm, Phase 3 study that randomized 942 patients undergoing highly emetogenic chemotherapy (HEC) treatment for various tumor types. HEC regimens were defined by the 2011 American Society of Clinical Oncology (ASCO) guidelines and included cisplatin regimens of ≥ 50 mg/m^2 among other agents. MAGIC, which was conducted entirely in the U.S. at 83 community oncology centers, is the first and only Phase 3 CINV study in which patients in the comparator arm received the standard-of-care, three-drug regimen used for prophylaxis in a HEC population. On day 1 of the first treatment cycle, patients were randomized 1:1 to receive either: (i) SUSTOL administered subcutaneously plus IV fosaprepitant 150 mg and IV dexamethasone 12 mg; or (ii) IV ondansetron 0.15 mg/kg (up to 16 mg) plus IV fosaprepitant 150 mg and IV dexamethasone 12 mg. On day 2 following administration of chemotherapy, all study patients received oral dexamethasone 8 mg once (QD), and, on days 3 and 4 following administration of chemotherapy, all study patients received oral dexamethasone 8 mg twice daily (BID). The primary endpoint of the study was the proportion of patients who achieved a Complete Response, defined as no emesis and no rescue medications, during the delayed-onset phase of CINV, occurring 24-120 hours following administration of HEC agents.

About SUSTOL® for Chemotherapy-Induced Nausea and Vomiting

Heron's lead investigational product candidate, SUSTOL ® (granisetron injection, extended release), is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting (CINV) following the administration of moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC) agents. SUSTOL is not approved by the FDA or any other regulatory authority. Affecting 70-80% of patients undergoing chemotherapy, CINV is one of the most debilitating side effects of such treatments, often attributed as a leading cause of premature discontinuation of cancer treatment. Injectable 5-hydroxytryptamine type 3 (5-HT$_3$) receptor antagonists have been shown to be among the most effective and preferred treatments for CINV. However, an unmet medical need exists for patients suffering from CINV during the delayed-onset phase, which occurs on days 2-5 following administration of chemotherapy agents. For delayed-onset CINV, only one injectable 5-HT$_3$ receptor antagonist is approved for use following the administration of MEC agents, and no 5-HT$_3$ receptor antagonists are approved for use following administration of HEC agents. SUSTOL contains the 5-HT$_3$ receptor antagonist granisetron, selected due to its broad use by physicians based on a well-established record of safety and efficacy. SUSTOL is formulated with the Company's proprietary Biochronomer® drug delivery technology and, in clinical trials, has been shown to maintain therapeutic drug levels of granisetron for up to five days with a single subcutaneous injection.

SUSTOL was the subject of a recently completed, multi-center, placebo-controlled, Phase 3 study in patients receiving HEC agents known as MAGIC. MAGIC evaluated the efficacy and safety of SUSTOL as part of a three-drug regimen with the intravenous (IV) neurokinin-1 (NK$_1$) receptor antagonist fosaprepitant and the IV corticosteroid dexamethasone for the prevention of delayed nausea and vomiting in patients receiving HEC. MAGIC, which was conducted entirely in the U.S., is the only Phase 3 CINV study to-date to use as a comparator the currently recommended, standard-of-care, three-drug regimen for CINV prophylaxis in a HEC population: a 5-HT$_3$ receptor antagonist (in this case ondansetron), fosaprepitant and dexamethasone. The study's primary endpoint was achieved. Specifically, the percentage of patients who achieved a Complete Response was significantly higher in the SUSTOL arm compared with the comparator arm (p=0.014). Heron intends to resubmit its New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA) in mid-2015. SUSTOL is not approved by the FDA or any other regulatory authority.

About HTX-019 for Chemotherapy Induced Nausea and Vomiting

HTX-019 is a proprietary intravenous formulation of aprepitant, a neurokinin-1 (NK$_1$) receptor antagonist for the prevention of CINV. NK$_1$ receptor antagonists are typically used in combination with 5-HT$_3$ receptor antagonists. At present, the only injectable NK$_1$ receptor antagonist approved in the U.S. contains polysorbate 80, a surfactant, which may cause hypersensitivity reactions, infusion site reactions or other adverse reactions in some patients. Heron's formulation for HTX-019 does not contain polysorbate 80 and may have a lower incidence of certain types of adverse reactions than reported with the commercially available injectable NK$_1$ receptor antagonist. Heron intends to file an NDA for HTX-019 using the 505(b)(2) pathway in the second half of 2016.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a biotechnology company using its proprietary technology and innovative efforts to develop products to address unmet medical needs. The Company's proprietary Biochronomer drug delivery technology is designed to improve the therapeutic profile of injectable pharmaceuticals. The Company's product development efforts focus on identifying current therapies with the potential to be reformulated to expand or extend therapeutic effect or duration of action, minimize drawbacks or to apply new delivery methods. In addition, we continually evaluate potential development programs, technologies and product candidates that may be complementary to or synergistic with our existing programs and product development goals.

Forward-Looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. Heron Therapeutics cautions readers that forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include those associated with: results of the HEC study, the New Drug Application (NDA) resubmission for SUSTOL, potential regulatory approval of SUSTOL and the timing for such approval, if approved at all; the progress in research and development of HTX-019, HTX-011, HTX-003 and our other product candidate programs, including the timing of planned toxicology and clinical studies; safety and efficacy data from our clinical studies that may not warrant further development of our product candidates; the launch and acceptance of SUSTOL and new products

generally; our financial position and our ability to raise additional capital to fund operations if necessary or to pursue additional business opportunities; strategic business alliances we may pursue or the potential acquisition of other products or technologies; and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. We caution investors that forward-looking statements reflect our analysis only on their stated date. We do not intend to update them except as required by law.

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